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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,750	03/10/2004	Kazuhiro Kondo	SUSU122563	7201
26389	7590	01/11/2006	EXAMINER	
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			LUNDGREN, JEFFREY S	
			ART UNIT	PAPER NUMBER
			1639	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,750	<b>Applicant(s)</b> KONDO ET AL.	
	<b>Examiner</b> Jeffrey S. Lundgren	<b>Art Unit</b> 1639	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>see office action</u> . | 6) <input type="checkbox"/> Other: _____  |

***Double Patenting  
Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-6) in the reply filed on October 7, 2005, is acknowledged. Accordingly, claims 1-6 will be examined on the merits, and claims 7-9 are withdrawn from consideration as being drawn to a non-elected invention.

***Objection of the Specification Under 37 C.F.R. §§ 1.821-1.825***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821(a)(1) and (a)(2). See, for example, the nucleotide sequence on page 32. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825 because this sequence contains greater than or equal to 10 nucleic acid molecules and does not have a SEQ ID NO. A thorough review by Applicants and correction throughout the application are required.

Applicants are also reminded that SEQ ID NOS are not required in Figures *per se*, however, the corresponding SEQ ID NOS then are required in the *Brief Description of the Drawings* section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicants are required to submit a new computer readable form sequence listing, a paper copy for the specification, statements under 37 CFR § 1.821(f) and (g), if there is a need to list additional sequences in the sequence listing.

Applicants are given the same response time regarding this failure to comply as that set forth to respond to this Office Action (*i.e.*, three months). Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

***Objection to the Abstract Under 37 C.F.R. § 1.72***

The abstract of the disclosure is objected to because it does not allow the public generally to determine quickly from a cursory inspection the nature and gist of the invention. Applicants should amend the abstract so that it corresponds to at least one of the independent claims being examined. For example, Applicants should describe how RecA introduces a target strand by

Art Unit: 1639

homologous recombination to a second dsDNA, describe the relationship of Exonuclease I to the first strand nucleic acid of the triple stranded portion of the second dsDNA, and describe how the second dsDNA is preferentially selected. *See* 37 C.F.R. § 1.72. Should Applicants amend the claims in their next reply, the amended abstract should take into account any further limitations added to the broadest independent claim.

### ***Priority***

Applicants' claim to foreign priority, and receipt of papers submitted under 35 U.S.C. 119(a)-(d) are acknowledged, which papers have been placed of record in the file.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, and dependent claims 2 and 3, are indefinite because claim 1 recites the phrase "whose 3' terminal has a different sequence from that of the *second* dsDNA." Applicants have already established that the "third ss nucleic acid" is homologous to a portion of the second dsDNA. If Applicants intend to claim the difference with respect to the *first* dsDNA, appropriate amendment is required.

Claims 4, and dependent claims 5 and 6, are indefinite because the claims establish third, fourth and fifth nucleic acids, but do not establish a "second" nucleic acid. Correction is required.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

Art Unit: 1639

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,613,522. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed subject matter in the '522 patent is directed a method of enriching a first double stranded nucleic acid from a mixture of at least a first and second nucleic acids. The first and second nucleic acids are converted to first and second single stranded nucleic acids, and the second single stranded nucleic acid forms a triplex with RecA, and is regenerated with an exonuclease (see claim 7), and regeneration and enrichment of the first dsDNA.

In the instant invention, the role between the sample first and second nucleic acids and introduced target sequence that forms a triplex with RecA is reversed in comparison to the '522 patent. Accordingly, such an arrangement merely represents the "reversal of parts." See, *In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955), where prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; the mere reversal of such movement, so the clock moves with wheel,

Art Unit: 1639

was held to be an obvious expedient. Claim 2 is directed to a creating a circular DNA library; this limitation is met by claim the plasmid vector of claim 2.

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,613,522, in view of Stemmer *et al.*, U.S. Patent No. 5,834,252. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claimed subject matter in the '522 patent is directed a method of enriching a first double stranded nucleic acid from a mixture of at least a first and second nucleic acids. The first and second nucleic acids are converted to first and second single stranded nucleic acids, and the second single stranded nucleic acid forms a triplex with RecA, and is regenerated with an exonuclease (see claim 7), and regeneration and enrichment of the first dsDNA.

In the instant invention, the role between the sample first and second nucleic acids and introduced target sequence that forms a triplex with RecA is reversed in comparison to the '522 patent. Accordingly, such an arrangement merely represents the "reversal of parts." *See, In re Gazda*, 219 F.2d 449, 104 USPQ 400 (CCPA 1955), where prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; the mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient. Claim 2 is directed to a creating a circular DNA library; this limitation is met by claim the plasmid vector of claim 2.

However, the '522 patent does not explicitly claim self-ligation.

Stemmer teaches a method of for amplifying and detecting any target nucleic acid sequence contained in a nucleic acid or mixture thereof and for assembling large polynucleotides from component polynucleotides, each involving generating concatemers formed by PCR amplification of overlapping fragments. Stemmer uses and comments on number of routine DNA manipulations in the, including, the use of RecA, various hybridizations, various restriction enzymes, and self-ligation of circular DNA (see col. 2, lines 35-40).

One of ordinary skill in the art would have had a reasonable expectation of success in arriving at the invention claimed, because the claimed invention only varies by a well-known and routine approach to manipulating circular DNA, specifically, a particular type of ligation. One

Art Unit: 1639

of ordinary skill in the art would have recognized the advantages of carrying out self ligation in such a system instead of the use of the extra step and reagents required by adding a ligase. Accordingly, the invention as a whole was *prima facie* obvious at the time it was invented.

### ***Conclusions***

No claim is allowable.

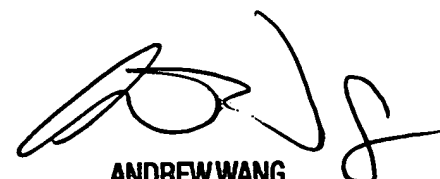
If Applicants should amend the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsius verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL



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